

**UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK**

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| In re Novartis and Par Antitrust Litigation | : | Case No. 1:18-cv-04361-AKH |
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| This Document Relates to:                   | : |                            |
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| All Actions                                 | : |                            |
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**MEMORANDUM OF LAW IN SUPPORT OF DEFENDANTS’ MOTION FOR HIPAA  
QUALIFIED PROTECTIVE ORDER**

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Defendants Novartis Pharmaceuticals Corporation, Novartis AG (“Novartis Defendants”) and Par Pharmaceutical, Inc. (“Par”), collectively, “Defendants”, request that the Court enter the attached protective order in order to allow third-party pharmacy benefits manager (“PBM”)<sup>1</sup> OptumRx (“Optum”) to produce documents and data in response to Novartis Defendants’ subpoena, dated October 11, 2019. The purpose of such a protective order is to accommodate Optum’s compliance with the Health Insurance Portability and Accountability Act (“HIPAA”), and it is at Optum’s request that Defendants thus seek entry of a HIPAA Qualified Protective Order.

Plaintiffs do not oppose this motion or the terms of the proposed order. Plaintiffs claim that the protective order is unnecessary because, in their view, Optum could redact or de-identify (*i.e.*, mask) any HIPAA-protected information. But redacting the documents at issue would be time consuming and costly for Optum, a third party, and also could render them unusable for the purpose Defendants seek it. HIPAA explicitly contemplates that parties such as Optum can make available protected health information during litigation discovery by means of a special protective order.<sup>2</sup> Defendants therefore respectfully request that the Court grant Defendants’ motion and enter the HIPAA Qualified Protective Order.

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<sup>1</sup> Pharmacy benefit managers are entities that contract with and perform pharmacy benefit responsibilities for insurers, administer drug formularies, and negotiate prescription medication pricing both with pharmaceutical manufacturers and with the pharmacies that dispense the medications. *See, e.g., In re Express Scripts/Anthem ERISA Litig.*, 285 F. Supp. 3d 655, 663 (S.D.N.Y. 2018). Discovery from such entities is routinely taken in pharmaceutical antitrust litigation such as this.

<sup>2</sup> Other PBMs from whom similar information has been subpoenaed—Express Scripts and CVS Caremark—currently are negotiating the scope of their productions, but have been informed of the proposed HIPAA Qualified Protective Order and do not object to its entry.

### **BACKGROUND**

In October 2019, Novartis Defendants subpoenaed Optum for information pertaining to persons and entities who purchased branded and generic Exforge through Optum. Specifically, Novartis Defendants sought Optum's transaction-level sales data for the Novartis medication Exforge and its generic versions, which are the subjects of Plaintiffs' claims against Defendants in this litigation. Defendants believe this information is relevant, including for purposes of class certification. Optum has agreed to produce the information, and at least for purposes of this motion, Plaintiffs have not disputed its relevance. Optum asserts, however, that it is prohibited from disclosing the information Defendants seek under HIPAA absent either a protective order or a notification sent to each customer. Defendants and Optum have accordingly agreed to the attached protective order, which is substantively similar to other such orders entered in cases such as these, including in this District. Plaintiffs do not object to any of its provisions, but as noted contend that it is unnecessary.

### **ARGUMENT**

HIPAA permits covered entities, such as PBMs, to disclose protected health information—*i.e.*, individually identifiable health information—only upon the entry of a qualified protective order (absent notice to each affected individual). *See* 45 C.F.R. §§ 160.103, 164.512(e)(1)(ii). HIPAA specifies that qualified protective orders must: (1) prohibit the parties from using or disclosing the protected health information for any purpose other than the litigation or a proceeding for which such information was requested; and (2) require the return to the covered entity or destruction of the protected health information (including all copies made) at the end of the litigation or proceeding. 45 C.F.R. § 164.512(e)(v).

These sections of HIPAA are understood to allow for the disclosure of protected health information during discovery. *Bayne v. Provost*, 359 F. Supp. 2d 234, 237 (N.D.N.Y. 2005)

(“[A] purpose of HIPAA was that health information, that may eventually be used in litigation or court proceedings, should be made available during the discovery phase.”); *Nw. Memorial Hosp. v. Ashcroft*, 362 F.3d 923, 925-26 (7th Cir. 2004) (“45 C.F.R. § 164.512(e) should be understood to . . . create a procedure for obtaining authority to use medical records in litigation.”).

Courts have broad discretion to enter protective orders under Rule 26(c) of the Federal Rules of Civil Procedure when good cause exists, *Dove v. Atl. Capital Corp.*, 963 F.2d 15, 19 (2d Cir. 1992), and it is well established that there is good cause for HIPAA Qualified Protective Orders because they permit parties discovery of otherwise protected health information while safeguarding its privacy. *See Brookdale Univ. Hosp. and Med. Ctr. Inc. v. Health Ins. Plan of Greater New York*, 2008 WL 4541014, at \*1, No. 07-CV-1471 (RRM)(LB) (E.D.N.Y. Oct. 7, 2008) (“[G]ood cause exists for the Protective Order . . . governing the confidentiality of [Protected Health Information], because protection is mandated by federal regulations governing the ‘Privacy of Individually Identifiable Health Information’”) (internal citations omitted); *Nat’l Abortion Fed’n v. Ashcroft*, 2004 WL 555701, at \*2-3 (S.D.N.Y. Mar. 19, 2004) (“HHS promulgated regulations to protect the privacy of protected health information . . . [and] explicitly addressed disclosure of protected health information during judicial or administrative proceedings.”).

HIPAA Qualified Protective Orders therefore are commonly entered by courts, including in pharmaceutical antitrust cases such as this. *See, e.g., In re Namenda Direct Purchaser Antitrust Litig.*, No. 15-cv-07488 (CM)(RWL) (S.D.N.Y. Dec. 8, 2016), ECF No. 123; *In re Asacol Antitrust Litig.*, No. 15-cv-12730 (DJC) (D. Mass. June 24, 2016), ECF No. 104; *Brookdale Univ. Hosp.*, 2008 WL 4541014, at \*1; *Tavares v. Lawrence & Mem’l Hosp.*, No.

3:11-CV-770 (CSH), 2012 WL 5929949, at \*2 (D. Conn. Nov. 27, 2012); *In re Zyprexa Prods. Liab. Litig.*, 254 F.R.D. 50, 53 (E.D.N.Y. 2008). In fact, at least one named Plaintiff in this case has previously stipulated to the entry of a HIPAA Qualified Protective Order in a case such as this. *See In re Namenda*, ECF No. 123 (reflecting that Rochester Drug Co-Operative, also a plaintiff here, stipulated to such an order).

There is good cause for entry of a HIPAA Qualified Protective Order here. Redacting the information Defendants seek would make it difficult if not impossible to track repeated transactions of a single purchaser. And, while Optum's transaction-level sales data could be de-identified such that a control number is used to track each purchaser, that would impose burden and cost on Optum, potentially requiring the hiring of a separate vendor. By contrast, entering the proposed order will avoid such burden and cost, while safeguarding privacy and satisfying the interests of judicial economy and efficiency. *See, e.g., Catzin v. Thank You & Good Luck Corp.*, 899 F.3d 77, 86 (2d Cir. 2018) (noting that judicial economy would not be served by requiring parties to expend additional years and dollars and that as "[t]he very first Rule of Civil Procedure provides, procedure in the district courts is meant to 'secure the just, speedy, and inexpensive determination of every action and proceeding.'" (citation omitted)). For their part, Plaintiffs will bear zero burden, cost or disadvantage of any kind from the entry of the requested HIPAA Qualified Protective Order.

Given that Defendants are entitled to discovery of Optum's transaction-level sales data, that redacting the information would make the information unusable, that de-identifying the information would be burdensome and costly, and that HIPAA contemplates the sort of discovery requested here, Defendants respectfully seek the entry of the proposed order, attached

hereto as Exhibit 1, that follows the requirements of HIPAA in order to permit disclosure of the protected health information to all parties for purposes of this litigation.

March 5, 2020

Respectfully submitted,

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# **Exhibit 1**



**UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF NEW YORK**

IN RE: NOVARTIS AND PAR ANTITRUST  
LITIGATION

This Document Relates to:

All Actions

1:18-cv-04361-AKH

**[PROPOSED] HIPAA QUALIFIED PROTECTIVE ORDER**

THIS COURT enters this protective order in accordance with requirements of the regulations promulgated under the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”), specifically 45 C.F.R. §§ 164.512(e)(1)(ii)(B), 164.512(e)(1)(v), to enable the production and limit the use or disclosure of “protected health information” (as defined below) in this Action for purposes of prosecuting or defending this action. Pursuant to Rule 26(c) of the Federal Rules of Civil Procedure and 45 C.F.R. §164.512(e)(1), the Court finds good cause for the issuance of a HIPAA qualified protective order and hereby ORDERS as follows:

1. Defendants have subpoenaed certain pharmacy benefit managers for data and documents pertaining to persons and entities who purchased branded and generic Exforge from them (hereinafter, “Purchasers”) for the purpose of defending this action. Thus, this Court finds there is sufficient need for a protective order to ensure the confidentiality of protected health information (as defined below).

2. The Parties and their attorneys are hereby authorized to receive, subpoena and transmit “protected health information” (as defined below) pertaining to the extent and subject to the conditions outlined herein.

3. For the purposes of this HIPAA qualified protective order, the term “protected health information” shall have the same scope and definition as set forth in 45 C.F.R. §§ 160.103

and 164.501; *i.e.*, protected health information is information that (a) has been created or received by a HIPAA covered entity or an employer; (b) relates to (i) the past, present, or future physical or mental condition of an individual; (ii) the provision of care to an individual, or the payment for care provided to an individual; and (iii) identifies the individual or which reasonably could be expected to identify the individual.

4. All “covered entities” (as defined by 45 C.F.R. § 160.103) are hereby authorized to disclose protected health information pertaining to Purchasers to attorneys representing the Plaintiffs and Defendants (collectively, the “Parties”) in the above-captioned litigation.

5. The Parties and their attorneys shall be permitted to use or disclose the protected health information of Purchasers only for purposes of prosecuting or defending this action, including any appeals of this case. This includes, but is not necessarily limited to, disclosure to their attorneys, experts, consultants, court personnel, court reporters, copy services, trial consultants, and other entities or persons involved in the litigation process.

6. The Parties agree that they will not use or disclose Purchasers’ protected health information for any purpose other than this litigation. Prior to disclosing Purchasers’ protected health information to persons involved in this litigation, the Parties and their attorneys shall inform such persons that Purchasers’ protected health information may not be used or disclosed for any purpose other than this litigation. Counsel shall take reasonable steps to ensure that persons receiving Purchasers’ protected health information do not use or disclose such information for any purpose other than this litigation.

7. Within 45 days after the conclusion of the litigation, including appeals, the Parties, their attorneys, and any person or entity in possession of protected health information received from counsel pursuant to paragraph four of this Order, shall return Purchasers’

protected health information to the covered entity or destroy any and all copies of protected health information pertaining to Purchasers, except that counsel are not required to secure the return or destruction of protected health information submitted to the Court.

8. This Order does not control or limit the use of protected health information pertaining to Purchasers that comes into the possession of the parties or their attorneys from a source other than a “covered entity”, as that term is defined in 45 C.F.R. § 160.103.

9. Nothing in this Order authorizes counsel for the Parties to obtain medical records or information through means other than formal discovery requests, subpoenas, depositions, pursuant to a patient authorization, or other lawful process.

10. This Order does not authorize either party to seal Court filings or Court proceedings. The Court will make a good cause determination for filing under seal if and when the parties seek to file Purchasers’ protected health information under seal.

**SO ORDERED**

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The Honorable Alvin K. Hellerstein  
United States District Judge

Dated: